K080123

Wako Wako Diagnostics

JUL 17 2008

SECTION 9

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is K080123.

807.92 (a)(1): Name: **Wako Diagnostics**
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Contact: **Peter Panfili, Ph.D.**

807.92 (a)(2): Device name- trade name and common name, and classification

Trade Name:
APOLOWAKO HbA1c and APOLOWAKO GLU

Common Name:
Test system for individual reporting of:
- HbA1c
- Glucose

Classification:
Glycosylated hemoglobin assay, Section 864.7470, Class II
Glucose Test System, Section 862.1345, Class II

807.92 (a)(3): Identification of the legally marketed predicate device
CHOLESTECH LDX and CHOLESTECH GDX, Cholestech Corporation, Hayward, CA cleared under K904082 (LDX), K904082 (Glucose) and K011933 (GDX).

807.92 (a)(4): Device Description
The APOLOWAKO analyzer is a fully-integrated POC test system that can perform up to six analytical tests per individual sample. For the HbA1c test, whole blood, and not plasma, is used. For all other tests, the analyzer

automatically separates plasma from whole blood for testing. Once the plasma has been separated, it is transferred to a cell on a measurement disk where the chemical reactions take place. The analyzer uses liquid reagents which are packaged into kits. Each kit contains 2 reagent units. Each unit is composed of two reagents and a calibrator. All of the reagents have a reagent information tag applied to the back of each bottle which controls the reagent parameters and conditions such as, calibration, reagent quantity, shelf-life, and lot number. The instrument contains an automated liquid dispenser, temperature controlled reagent carrousel, analysis compartment, and sample holder. The instrument is designed to automatically and constantly monitor the reagents, dispensing system, measurement disk, and measurement process to ensure that no erroneous results are shown. The APOLOWAKO HbA1c and APOLOWAKO Glucose include hemoglobin A1c and glucose test reagents. The test system is designed for professional use and consists of a small table top instrument (31 cm wide x 47.5 cm high x 56 cm deep, weight: 25 kg).

807.92 (a)(5): Intended Use

The APOLOWAKO HbA1c and APOLOWAKO Glucose are for the quantitative determination of hemoglobin A1c (HbA1c) % and glucose in whole blood samples.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Similarities / Differences between the APOLOWAKO HbA1c, APOLOWAKO Glucose and Established Predicate Devices (Cholestech LDX and GDX)

CHARACTERISTIC	APOLOWAKO Analyzer	Cholestech LDX & GDX Systems
Intended Use	The APOLOWAKO HbA1c and APOLOWAKO Glucose are for the quantitative determination of hemoglobin A1c (HbA1c) % and glucose in whole blood samples.	"The Cholestech GDX A1C Test…is indicated for monitoring the average blood glucose levels of people with diabetes as an indicator of overall blood glucose control." "…for the quantitative determination of glucose in whole blood."
Indications for Use From CFR 864.7470 and CFR 862.1345	Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient.	Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient.

Wako Diagnostics

	Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient. Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia.	Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient. Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia.
Sample	Whole blood	Whole blood
Sample Preparation	Venous whole blood sample	Finger stick or venous whole blood sample
Calibration	Calibration is required at the time the reagent is opened and lasts for 28 days or until expiration date.	No calibration is performed by the user.
Methodology	Colorimetric, enzyme-based (glucose); absorbance, immune inhibition (HbA1c)	Colorimetric, affinity chromatography
Testing Environment	Professional use, point-of-care	Prescription home use (A1c) Professional use, point-of-care (glucose)

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Reportable range	**HbA1c:** 3-16.5% **Glucose:** 18-350 mg/dL	**HbA1c:** 4-15% **Glucose:** 50-500 mg/dL
Precision	**HbA1c:** Total imprecision is 3% or less across a range of 4.8% to 15.2% (mean values). **Glucose:** Total imprecision is less than 2% CV across a range of 72 mg/dL to 540 mg/dL (mean values).	**HbA1c:** Total imprecision less than 4% across a range of 5.7% to 9.4% (mean values). **Glucose:** Total imprecision less than 6.5% across a range of 103 mg/dL to 127 mg/dL.
Linearity	Assay linear throughout reportable range	Assay linear throughout reportable range
Interfering Substances	No interference from high levels of bilirubin (conjugated and unconjugated), triglycerides, hemoglobin (for glucose only), sodium fluoride, (glucose only), heparin sodium, EDTA-2Na, ascorbic acid and others. Labile HbA1c, carbamylated hemoglobin or acetylated hemoglobin has no influence on the HbA1c assay.	For HbA1c: No interference was seen from high levels of bilirubin, acetylsalicylic acid, caffeine, acetominophenol, and hydroxyzine dihydroxychloride. Elevated lipid may interfere and cause low results in this type of assay. For glucose: There may be a 6-7% difference in the glucose levels of fingerstick and venous blood. (23 other substances had no effect).

807.92 (b)(1): Brief Description of Non-clinical Data

Evaluations were performed for within-day imprecision, between-day imprecision, linearity, and interfering substances. Those resulting data are summarized below.

HbA1c

Within-day imprecision, when evaluated at three levels of hemoglobin (low- 4.8 %, intermediate- 7.7 %, and high- 16.7 %), ranged from 1.2 % CV to 1.5 % CV. Between-day imprecision, when evaluated in duplicate over 10 days ranged from1.5 % CV to 3.0 % CV.

Results from linearity studies demonstrated that the hemoglobin A1c ratio (%) is linear throughout the reportable range.

Results from an interference testing showed hemoglobin A1c assay is not affected by high levels of glucose or bilirubin (conjugated or unconjugated).

Glucose

Within-day imprecision, when evaluated at three levels of glucose (low- 56 mg/dL, intermediate- 97 mg/dL, and high- 588 mg/dL), ranged from 0.6 % CV to 1.8 % CV. Between-day imprecision, when evaluated with in duplicate over 10 days, ranged 0.7 % CV to 1.1 % CV.

Results from linearity studies demonstrated that the glucose is linear throughout the reportable range.

Results from an interference testing showed that the glucose is not affected by high levels of hemoglobin, bilirubin (conjugated or unconjugated), triglycerides, ascorbic acid, EDAT-2Na, heparin sodium, or sodium fluoride.

807.92 (b)(2): Brief Description of Clinical Data

The method comparison study shows substantial equivalence to FDA cleared comparison methods for HbA1c and Glucose. For each analyte at least 387 (352 for HbA1c) broadly distributed samples showed statistically significant correlation to the reference method with slopes approaching 1.0 and y-intercepts approaching zero. APOLOWAKO results were collected under rigorous conditions sufficient to meet the requirements for CLIA Waiver. The results show correlation coefficients of 0.99 or better for each assay.

807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing

Non-clinical and clinical testing was performed for the APOLOWAKO HbA1c and APOLOWAKO Glucose. The test system was shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Wako Chemicals USA, Inc.
c/o Mr. Peter Panfili
665 Clyde Avenue, Suite B
Mountain View, CA 94043

JUL 17 2008

Re: k080123
Trade/Device Name: APOLOWAKO Glu and APOLOWAKO HbA1c
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR and LCP
Dated: June 24, 2008
Received: June 30, 2008

Dear Mr. Panfili:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number ~~(800) 638-2041 or (240) 276-3150 or at its Internet address at~~ http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indication for Use

510(k) Number (if known): K080123

Device Name: The APOLOWAKO HbA1c and APOLOWAKO GLU

Intended Use

The APOLOWAKO HbA1c and APOLOWAKO Glucose are for the quantitative determination on the APOLOWAKO analyzer of hemoglobin A1c (HbA1c) % and glucose in whole blood samples.

Indications for Use

HbA1c- Measurement of % HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus.

Glucose- Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and pancreatic islet cell carcinoma.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080123